DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District

1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

T2092M

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 30, 1998

Our Reference: 2953809

Stephen J. Rasmussen, Owner
Roundman's Smoke House & Wholesale Meats
412 North Main Street
Fort Bragg, California 95437

WARNING LETTER

Dear Mr. Rasmussen:

On May 27 and 29, 1998, FDA Investigator Darla Bracy conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations (CFR), Part 123, and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deviations which constitute violations of the Federal Food, Drug and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

In conjunction with the inspection, a sample of smoked albacore, represented by FDA FACTS No. 7880, was collected and analyzed by FDA. Results of the analysis by the FDA laboratory showed that the smoked albacore contains 69 parts per million (ppm) and 65.6 ppm of nitrites, additional and check analysis respectively. The product of smoked albacore is adulterated under Section 402(a)(2)(C) because it contains excessive nitrites, an unsafe food additive within the meaning of Section 409 of the Act. The presence of nitrites at levels greater than 10 ppm does not comply to its approved use as a color fixative in smoked cured tuna, in accordance with 21 CFR 172.175. Nitrites in smoked cured tuna greater than 10 ppm have not been proven to be effective and safe for its intended use. Adulterated foods are subject to

seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k). Failure to correct the violation may result in legal sanctions such as seizure and/or injuction without further notice.

During the inspection, the FDA investigator also observed shortcomings in your HACCP system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. At the conclusion of the inspection, the FDA investigator provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501), and the FDA 483 (Inspectional Observations) and discussed her findings with you. Briefly, these deviations are as follows:

1. The food safety hazard of *Clostridium botulinum* toxin formation was not identified in your HACCP plans for smoked salmon and smoked tuna as required by 21 CFR 123.6(c)(1).

2. Neither of your HACCP plans for smoked salmon nor for smoked tuna have control measures for *C. botulinum* toxin formation at the brining step as required by 21 CFR 123.6(b). During the inspection, FDA also collected a sample of hot smoked salmon (FDA FACTS No. 7879). The average water phase salt obtained on the sample was 1.58 percent and the average nitrite level was 4 ppm. To control toxin formation by brining, it is recommended in the FDA Fish & Fishery Products Hazards & Controls Guide: Second Edition, that the percent water phase salt for vacuum packaged smoked fish or smoke-flavored fish, be not less than 3.5 percent in the loin muscle, or where permitted--as in the case of salmon, but not tuna--the combination of 3.0 percent water phase salt in the loin muscle and not less than 100 ppm nitrite. Water phase salt below the guidelines would not provide a preventive control for *C. botulinum* toxin in a refrigerated, vacuum packaged, smoked fish or smoked-flavored fish product.

3. Your HACCP plans for smoked fish do not have control measures for *C. botulinum* toxin formation during the cooling step after hot smoking and during the distribution of the finished product as required by 21 CFR 123.6(b).

4. Your HACCP plans for smoked fish do not have adequate verification procedures to address the hazard of *C. botulinum* toxin formation as required by 21 CFR 123.8. There is no documented evidence that brining/drying process was established by a scientific study to achieve a water phase salt level that inhibits *C. botulinum* growth and toxin formation.

5. The verification procedure at the filleting step to control histamine formation in tuna is inadequate as required by 21 CFR 123.6)b). Although sensory examination is an effective tool to screen fish for spoilage odors caused by time/temperature abuse, it will not detect the presence of histamines. Your firm should perform histamine testing to ensure that the hazard of histamine formation is adequately controlled.

6. Your HACCP plans and records do not have the name and location of the processor as required by 21 CFR 123.9(a).

7. Your HACCP plans are not signed and dated as required by 21 CFR 123.6(d).

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP regulations, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response, or a request for additional time, to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: Mr. and Mrs. Steve Scudder, Co-owners